

### **Remarks**

Claims 100-102 and 130-185 are now pending. Claims 160-185 are added and claims 136-138, 146, 149, 150, and 159 are amended herein without any prejudice or disclaimer of any previously claimed subject matter. Support for claims 183-185 can be found on page 66 of the specification. In the Office Action dated August 27, 2003, the Examiner did not acknowledge Applicants' Supplemental Amendment of August 26, 2003. It is assumed that while the Amendment was filed before the mailing date of the Office Action, it did not reach the Examiner until after he issued the Action. Applicants respectfully request the Examiner acknowledge entry of the August 26, 2003 Amendment, and enter the new amendments and claims presented herein. The claims presented in this Response are based on the assumption that the August 26, 2003 amendments have already been entered.

### **Supplemental Information Disclosure Statement**

On June 23, 2003, Applicants submitted a Supplemental Information Disclosure Statement, citing three U.S. patents, eighteen International Patent Publications, and two articles. Applicants respectfully request the Examiner acknowledge entry and consideration of said Supplemental Information Disclosure Statement.

On August 26, 2003, Applicants submitted another Supplemental Information Disclosure Statement, citing U.S. Patent Publication Nos. 2002/0147160 A1 and 2003/0060400 A1, as well as International Patent Publication No. WO 03/051899 A1. Applicants respectfully request the Examiner acknowledge entry and consideration of said Supplemental Information Disclosure Statement.

In addition, pursuant to the duty of disclosure under 37 CFR §§ 1.56, 1.97 and 1.98, Applicants cite the publications listed on the accompanying PTO-1449. Copies of all listed references are enclosed. The citation of this information does not constitute an admission of

priority or that any cited item is available as a reference, or a waiver of any right the Applicants may have under the applicable statutes, regulations and Rules of Practice in patent cases, or otherwise. Applicants respectfully request the Examiner acknowledge entry and consideration of the present Supplemental Information Disclosure Statement and Form 1449 submitted with this response.

The Examiner's attention is specifically directed to U.S. Patent Application No. 09/863,816, filed May 23, 2001, now published as U.S. Patent Application Publication No. 2003/0060400 A1, describing methods to treat flaviviruses and pestiviruses comprising administering  $\beta$ -D-pyrimidine compounds that are di-substituted in the 2'-position with two non-hydrogen substituents. Applicants have filed a Terminal Disclaimer in that case, disclaiming the terminal portion of any patent that issues from the '816 application that extends beyond the term of the present application. A copy of the Terminal Disclaimer is enclosed.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 89, 90, and 130-139 presented in the Amendment mailed June 6, 2003, were rejected under 35 U.S.C. § 112, second paragraph, allegedly because the variable  $R^3$  is indefinite. Applicants have cancelled claims 89 and 90 and has amended claims 130-139 in a manner that renders the present rejection moot. In claim 146 as now presented, there is no  $R^2$  or  $R^3$  substituent.

Rejections under 35 U.S.C. § 102

Claim 86 presented in the Amendment mailed June 6, 2003, was rejected under 35 U.S.C. § 102, allegedly because it is anticipated by U.S. Patent No. 6,348,587 ("the '587 patent"), which teaches numerous 2'-fluoronucleosides for the treatment of hepatitis C virus (HCV) infection. While this claim is no longer pending, Applicants would like to point out that in order to

constitute anticipation, each and every element of the claim must be disclosed by the prior art reference. The '587 patent does not specifically disclose the 2'-disubstituted nucleosides as presently claimed. The '587 patent does disclose a 2'-fluoro-2'-phenylselenyl nucleoside, which is used only as a precursor in the synthesis of 2'-fluoro-2',3'-dideoxy-2',3'-didehydro-nucleosides. Likewise, the '587 patent does not render the present claims obvious under 35 USC 103. One of ordinary skill in the art would not have been motivated nor would have had a reasonable expectation of success to use the 2'-fluoro-2'-phenylselenyl nucleoside, a precursor in the synthesis of 2'-fluoro-2',3'-dideoxy-2',3'-didehydronucleosides, for the treatment of hepatitis C virus infection. Therefore, the '587 patent does not anticipate or render obvious the use of 2'-di-substituted nucleosides for the treatment of hepatitis C virus infection as presently claimed.

The Examiner has acknowledged that claims 83, 100-102 and 140-145 are directed to allowable subject matter as the use of nucleoside compounds possessing a methyl group and dehydro substituents at the 2'-position for the treatment of hepatitis C virus is an unobvious modification of the prior art of record. In view of the currently presented claims, limited to methods for the treatment of hepatitis C virus infection in a host using  $\beta$ -D pyrimidine compounds that are di-substituted in the 2'-position with two non-hydrogen substituents, Applicants respectfully request that a Notice of Allowance be issued in this case.

Appl. No. 09/864,078  
Amdt. dated October 31, 2003  
Reply to Office Action of August 27, 2003

Applicants do not believe any fee is due with this Amendment and Response to Office Action and Transmittal of Supplemental Information Disclosure Statement; however, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account 11-0980.

Respectfully submitted,

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